

## REMARKS

Claims 23-35, 38, 41, 42, 44-47, and 49-79 are pending. Claims 23 and 60 are amended. No new matter has been added by virtue of the amendment, support being found throughout the specification as filed.

### I. 35 U.S.C. § 102 Rejections

Claims 23, 26-28, 31, 35, 38, 45-47, 49-51, 56, 58-63, and 70-79 are rejected under 35 U.S.C. § 102(b) over U.S. Patent Publication No. 2002/133184 to Lo Russo. Applicants respectfully traverse.

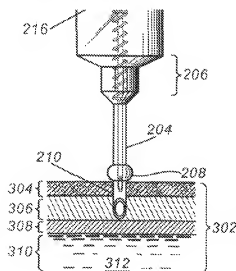
Independent claim 23, as amended, recites a method for treating an eye. According to Applicants' method, a device comprising a piercing member having lumen along a longitudinal axis of the piercing member and a cannula slidably disposed within the lumen is inserted into the eye. As set out, the step of inserting the device into the eye comprises penetrating the eye with the piercing member and advancing the piercing member through the eye transconjunctively until the distal end is within the vitreous humor of the eye. The cannula is then advanced through the piercing member lumen, through the vitreous humor, and towards a treatment site to pierce the treatment site. The eye is then treated by administering and/or aspirating material through the cannula.

Independent claim 27 recites a method of treating an eye, comprising piercing the eye with a piercing member and inserting the piercing member into the vitreous humor of the eye, the piercing member having a proximal end and a distal end and a lumen defined therebetween, angling the piercing member in any direction so as to guide the cannula to any treatment site within the eye, advancing a cannula through the piercing member lumen and beyond the distal end of the piercing member, guiding the cannula through the vitreous humor of the eye to the treatment site, and then treating the treatment site, thereby treating the eye.

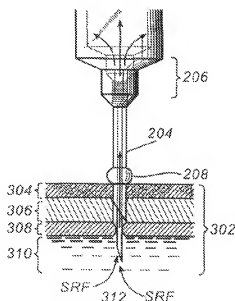
Independent claim 60, as amended, recites a method for treating an eye comprising inserting into an eye a device comprising an outer member having a proximal end and a distal end, a cannula slidably disposed within the outer member along a longitudinal axis of the outer

member, and a piercing member at the distal end of the outer member. As set out, the eye is pierced with the piercing member, and the piercing member and at least a portion of the outer member is advanced into the eye transconjunctively. The cannula is then advanced through the outer member and beyond the distal end through the vitreous humor of the eye to the treatment site. The eye is then treated by administering and/or aspirating material through the cannula.

Lo Russo, on the other hand, describes a device and method for performing transscleral cautery and subretinal drainage. As shown in Figs. 4A and 4B (reproduced, in part, below) and as described at [0056]-[0060], the device is inserted into the eye and is passed through the following layers: sclera 304, choroid 306, retinal pigment epithelium (RPE) 308, and subretinal space 310. Transscleral cautery is performed by heating the cautery section 210 [0057]. Subretinal drainage is performed by allowing the inner needle section 314 to penetrate through the RPE 308 and into the subretinal space 310, as shown in Fig. 4B [0060]. Applicants note that the RPE is the pigmented cell layer just outside the retina that nourishes retinal visual cells.

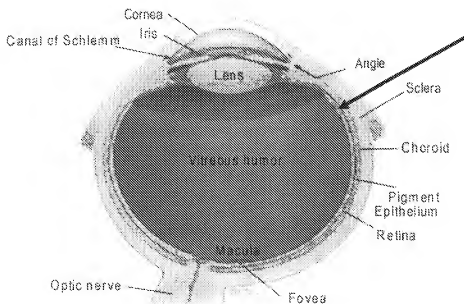


**Fig. 4A**



**Fig. 4B**

Clearly, Lo Russo never teaches or suggests either (1) piercing the eye with a piercing member and inserting the piercing member into the vitreous humor of the eye or (2) guiding the cannula through the vitreous humor of the eye to the treatment site, as recited in independent claims 23, 27, and 60. No portion of Lo Russo's device ever enters the vitreous humor — the clear gelatinous substance that fills the eyeball between the retina and the lens. Rather, Lo Russo uses a completely different method and entry approach by accessing the retina through the back or side portion of the eye and, thus, never enters the vitreous humor (e.g. as shown in Figs. 4A and 4B of Lo Russo and as depicted in the Figure below showing the eye with the vitreous humor).



Further, Lo Russo never teaches or suggests a method wherein a piercing member is inserted into the vitreous humor of the eye and the piercing member is angled in any direction so as to guide the cannula within the piercing member to any treatment site within the eye, as further recited in claim 27. Lo Russo is completely silent with respect to angling a piercing member at any point during the process.

Thus, claims 23, 27, and 60 are clearly not anticipated by Lo Russo. Claims 24-26, 28, 31, 35, 38, 45-47, 49-51, 56, 58-59, 61-63, and 70-79 depend from claims 23, 27, and 60 and, thus, also are not anticipated by Lo Russo. Reconsideration and withdrawal of the rejection is respectfully requested.

## 2. 35 U.S.C. § 103 Rejections

Claims 24, 25, 29, 30, 32-34, 41, 42, 44, 48, 52-55, 57, 62, 64, and 66-79 been rejected under 35 U.S.C. § 103(a) as being unpatentable over Lo Russo, Paques et al (US Pub 2003/0171722), and Bowman et al (US Patent 6,378,526). Applicants respectfully traverse the rejection.

As set forth above, Lo Russo at least fails to teach or suggest (1) piercing the eye with a piercing member and inserting the piercing member into the vitreous humor of the eye, (2) guiding the cannula through the vitreous humor of the eye to the treatment site, and (3) inserting the piercing member into the vitreous humor of the eye angling the piercing member in any direction so as to guide the cannula within the piercing member to any treatment site within the eye, as recited in independent claims 23, 27, and 60.

Further there is absolutely no motivation to modify Lo Russo so as to insert the piercing member into the vitreous humor or to advance the inner cannula through the vitreous humor. Rather, Lo Russo is directed to a device and method for transscleral cautery and subretinal drainage. Thus, Lo Russo's device is only inserted within the sclera and RPE. There is no motivation to further advance Lo Russo's piercing member or inner cannula beyond the treatment layers (sclera and RPE) and into the vitreous humor, as recited in Applicants' claims 23, 27, and 60.

Applicants further note that the vitreous humor, in which Applicants' piercing member is inserted, is a gelatinous substance that allows for the angling of the piercing member (and, thus, the distal end of the piercing member) such that the cannula can be advanced through the piercing member to any treatment site within the eye. On the other hand, Lo Russo's outer member ("piercing member") is positioned within the sclera, choroid, and retina (see Figs. 4A,

4B, 3A, 3B). The sclera is a tough, opaque tissue. The choroids is a layer of blood vessels. The retina is a multi-layered sensory tissue. Thus, Lo Russo's outer member (and, thus, the sharpened distal end of Lo Russo's outer member) could not be angled within these tissues so as to guide an inner member to any treatment site within the eye, as recited in Applicants' claim 27. Thus, there is absolutely no teaching or suggestion to modify Lo Russo so as to angle Lo Russo's piercing member as taught by Applicant nor is there any reasonable expectation of success in doing so.

Paques and Bowman do not remedy these deficiencies and, in any event, as noted above there would be no motivation or expectation of success to modify Lo Russo so as to provide Applicants' method. Bowman describes a simple tubular device that is used to inject and agent into the sclera and which never enters the vitreous humor of the eye. Paques' device is cited for the delivery of steroids, genetic material, or pharmaceuticals to the eye by inserting a handpiece through an incision that is surgically made to allow for insertion of the handpiece. Thus, Paques does not teach or suggest penetrating an eye using a piercing member (Paques' handpiece is not a piercing member and does not pierce the eye) and advancing the piercing member through the eye through the vitreous humor. A needle 4 "carried by" the handpiece is used to pierce a blood vessel within the eye. However, this needle 4 is not slidably received within the handpiece and, thus Paques does not teach or suggest advancing the needle through the handpiece through the vitreous humor, as recited by Applicants'. Paques further describes a flexible tube 8 that is movable within the needle 4. However, this flexible tube does not pierce the treatment site. Rather, according to Paques, the needle pierces a blood vessel and, after the needle is within the blood vessel, the flexible tube is advanced through the needle inside of the blood vessel.

Clearly, no combination of Lo Russo, Paques, and Bowman would have resulted in Applicants' claimed methods. Accordingly, independent claims 23, 27 and 60 are patentable over Lo Russo, Paques, and Bowman. Claims 24, 25, 29, 30, 32-34, 41, 42, 44, 48, 52-55, 57, 62, 64, and 66-79 depend from claims 23, 27, and 60 and, as such, are patentable over Lo Russo, Paques, and Bowman. Reconsideration and withdrawal of the rejection is respectfully requested.

## CONCLUSION

Applicants believe that additional fees are not required in connection with the consideration of the within matter. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105**.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

Dated: June 18, 2008

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